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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/719,737	06/29/2001	Paolo Renzi	701826051150	4150

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EXAMINER
LACOURCIERE, KAREN A

ART UNIT	PAPER NUMBER
1635	9

DATE MAILED: 09/24/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/719,737	Applicant(s) RENZI, PAOLO	
	Examiner Karen Lacourciere	Art Unit 1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 41-76 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 41-76 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

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DETAILED ACTION

Claim Objections

The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Misnumbered claims 1-36 (submitted in the preliminary amendment filed December 15, 2000, along with the request to proceed to the national stage) have been renumbered 41-76.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 41-45, drawn to an antisense oligonucleotide targeted to a common subunit of IL-3, IL-5 and GM-CSF receptors.

Group II, claim(s) 41-49 and 60-63, drawn to a compositions comprising an oligonucleotide targeted to a common subunit of IL-3, IL-5 and GM-CSF receptors and an oligonucleotide targeted to a common subunit of the IL-4 and IL-13 receptors.

Group III, claim(s) 41-76, drawn to a composition comprising an antisense oligonucleotide targeted to a common subunit of IL-3, IL-5 and GM-CSF receptors and an oligonucleotide targeted to a common subunit of the IL-4 and IL-13 receptors and an oligonucleotide targeted to a nucleic acid encoding a CCR3 receptor.

Group IV, claim(s) 41-45, 50-55 and 68-72, drawn to a composition comprising an antisense oligonucleotide targeted to a common subunit of IL-3, IL-5 and GM-CSF receptors and an oligonucleotide targeted to a nucleic acid encoding a CCR3 receptor.

Group V, claim(s) 56-59 and 73-76, drawn to a composition comprising an oligonucleotide targeted to a common subunit of the IL-4 and IL-13 receptors and an oligonucleotide targeted to a nucleic acid encoding a CCR3 receptor.

Additionally, for each of Groups I-V, listed above, Applicant must elect a single antisense composition, by sequence, for prosecution of the instant case. Specifically, if the elected invention includes antisense targeting a common subunit of IL-3, IL-5, and GM-CSF, applicant must elect SEQ ID NO: 9, 10, 11, 12, 13, 14, 15 or 16, a common subunit of IL-4 and IL-13 Applicant must elect SEQ ID NO: 1, 2, 3, 4, 5, 6 or 7, CCR3 receptor Applicant must elect SEQ ID NO: 18, 20, 22 or 23. If Applicant should elect a Group wherein the antisense composition comprises antisense targeted to multiple targets, Applicant must elect **a single combination** of SEQ ID NO:'s for prosecution in the instant case.

The inventions listed as Groups I-V do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Each of the inventions listed as Group I-V is considered to be a separate invention because they do not share a common structural feature, for example, the inventions listed as Groups I-V comprise antisense which target different biological targets. For example, Group I does not require antisense targeted to a common subunit of IL-4 and IL-13, as required for each of Groups II-V. Group III does not require an antisense targeted to CCR3 receptor, as required for Groups II and IV and V. Group IV does not require an antisense targeted to a common subunit of the IL-4 and IL-13 receptors, as required by Groups II, II and V. Group V does not require an antisense targeted to IL-3, IL-5 and GM-CSF receptors, as required for Groups I, II, II and IV. Group II requires an antisense targeted to a common subunit of IL-3, IL-5 and GM-CSF receptors and a CCR3 receptor and a common subunit of IL-4 and IL-13, which is not a requirement of any of Groups I and II-V.

Additionally, this international searching authority considers that the international application does not comply with the requirements of unity of invention (Rules 13.1, 13.2, and 13.3) for the reasons indicated below:

According to the guidelines in Section (f)(i)(a) of Annex B of the PCT Administrative Instructions, the special technical feature as defined by PCT Rule 13.2 shall be considered to be met when all the alternatives of a Markush-group are of similar nature.

For chemical alternatives, such as the claimed antisense sequences, the Markush group shall be regarded as being of similar nature when
(A) all alternatives have a common property or activity and
(B)(1) a common structure is present, i.e, a significant structure is shared by all of the alternatives or
(B)(2) in cases where the common structure cannot be the unifying criteria, all alternatives belong to an art recognized class of compounds in the art to which the invention pertains.

The individual antisense sequences recited in the claims are considered to be each separate inventions for the following reasons:

the sequences do not meet the criteria of (A), common property or activity or (B)(2), art recognized class of compounds. Although the sequence target and modulate expression of the same gene, each antisense sequence behaves in a different way in the context of the claimed invention. Each sequence targets a different and specific region of their particular target gene and each sequence modifies (either increases or decreases) the expression of the gene to varying degrees Each member of the class cannot be substituted, one for the other, with the expectation that the same intended result would be achieved.

Further, although the sequences target the same gene, the sequences do not meet the criteria of (B)(1), as they do not share, one with another, a common core structure. Accordingly, unity of invention between the antisense sequences is lacking and each antisense sequence claimed is considered to constitute a special technical feature.

A telephone call was made to David Resnick on 09-19-2002 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim

remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen A. Lacourciere whose telephone number is (703) 308-7523. The examiner can normally be reached on Monday-Friday 8:30-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on (703) 308-0447. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 305-1935 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

KAREN LACOURCIERE
PATENT EXAMINER

Karen A. Lacourciere
September 23, 2002